MAR 1 6 2001

K003449

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Ulrich Alber GmbH & Co. KG
Sigmaringer Strasse 100
D-72458 Albstadt Germany

Date Summary Prepared:

September, 2000

2. Name of the Device:

e-motion Wheelchair Drive System (Power-Assist for Wheelchairs)

3. Predicate Device Information:

Power Wheelchair Conversion Kit (currently marketed as e·fix device), K#943789, Alber Technologies, Inc., Germany.

4. Device Description:

e·motion is a power conversion kit that turns a manual wheelchair into a power – assisted wheelchair. e·motion is a push-and-brake assist working in both directions.

The e·motion wheelchair drive system adds a power assist to a manual wheelchair. The system consists of two wheels, each incorporating a motor, control unit circuitry, and battery: these replace the original wheels of the manual wheelchair. Each e·motion wheel also has a special hand rim (push rim) that incorporates pressure sensors. Batteries are recharged using an ALBER charger, Model BCS2402; it includes two output cables, each one plugging into one of the wheel hubs. Plugging the battery charger cable into the wheel hub disables the motors, preventing the user from activating them.

When the user pushes on the hand rim (push rim) of the drive ring of the special wheel assembly, the hand rim pressure sensor causes the motor to activate the wheel.

e·motion wheels only operate when the user pushes on the hand rim (just like a manual wheelchair). If the user stops, the friction of his hand against the push rim slows the wheelchair down; the brake action is, thereby, enhanced by the motors.

The driving force is adjustable and the two wheels operate independently. The wheelchair can be driven forward or backward. Sensors also adjust braking action on inclines. The wheel locks of the manual wheelchair can be used to prevent the wheelchair from rolling (just like a manual wheelchair); they get adjusted to lock e·motion wheels during the installation. The wheel locks may also be used assisting a user in decelerating the wheelchair to a complete stop.

A socket is provided on the battery for connecting a charger.

5. Intended Use:

The e·motion Wheelchair Drive System is a Power Wheelchair Conversion Kit that adds a power assist to a manual wheelchair, thereby, turning a manual wheelchair into a power-assisted wheelchair. It is a push-and-brake assist working in both directions. The intended use is to provide mobility to persons limited to a seated position that are capable of operating a powered and manual wheelchair.

6. Comparison to Predicate Devices:

Please see attached comparison chart.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

All applicable requirements from the following voluntary standards were met:

ANSI/RESNA WC/02 Wheelchair Standard for Static Stability Testing
ANSI/RESNA WC/02 Wheelchair Standard for Dynamic Stability Testing
ANSI/RESNA WC/Vol. 2 Wheelchair Standard for EMC Testing (Section 21)

8. Discussion of Clinical Tests Performed:

Not applicable.

9. Conclusions:

The e·motion Wheelchair Drive System has the same intended use and similar technological characteristics as the predicate device, the e·fix Power Wheelchair Conversion Kit.

Moreover, the non-clinical testing and predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the e·motion wheelchair Drive System is substantially equivalent to the predicate device, the e·fix Power Wheelchair Conversion Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

Ulrich Alber GmbH & Co. KG
Ms. Susan D. Goldstein-Falk
Official Correspondent for Ulrich Alber GmbH & Co. KG
c/o mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K003449
Trade Name: E Motion Wheelchair Drive System (Power-Assist For Manual Wheelchairs)
Regulatory Class: II
Product Code: ITI
Dated: February 1, 2001
Received: February 5, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

alber

Rehabilitations -Technik

Exhibit B

510(k) Number (if known): K003449

Device Name: e·motion Wheelchair Drive System
(Power-Assist for Manual Wheelchairs)

Indications For Use:

The e·motion Wheelchair Drive System is a Power Wheelchair Conversion Kit that adds a power assist to a manual wheelchair, thereby, turning a manual wheelchair into a power-assisted wheelchair. It is a push-and-brake assist working in both directions. The intended use is to provide mobility to persons limited to a seated position that are capable of operating a powered and manual wheelchair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003449

Prescription Use ____ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**